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AMENDED IN ASSEMBLY JUNE 8, 2004
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AMENDED IN SENATE MARCH 24, 2003

SENATE BILL

No. 142

Introduced by Senator Alpert
(Principal coauthor: Assembly Member Cohn)
(Coauthors: Senators Kuehl, McPherson, and Speier)
~~*(Coauthor: Assembly Member Lieber)*~~
*(Coauthors: Assembly Members Lieber, Maddox, Maldonado,
Plescia, Richman, and Spitzer)*

February 6, 2003

An act to amend Sections 124977, 124980, 125000, and 125001 of the Health and Safety Code, relating to genetic testing.

LEGISLATIVE COUNSEL'S DIGEST

SB 142, as amended, Alpert. Genetic testing.

(1) The Hereditary Disorders Act, among other provisions, declares the intent of the Legislature that the state's hereditary disorders program activities are to be fully supported by fees collected for services provided by the program, unless otherwise provided. Existing law requires the department to charge a fee to all payers for any tests or activities performed pursuant to provisions relating to genetic disorder prevention services, including the Hereditary Disorders Act. Existing law requires that any fee charged for screening and followup services

provided to Medi-Cal eligible persons, health care service plan enrollees, or persons covered by disability insurance policies are to be paid directly to the Genetic Disease Testing Fund, a continuously appropriated fund, to be used for purposes of the Hereditary Disorders Act, subject to the terms and conditions of the applicable health care service plan or insurance coverage. Under existing law, all moneys collected by the department pursuant to the act must be deposited into the fund. In addition, on and after July 1, 2002, the State Department of Health Services is required to charge a fee for newborn screening and followup services, and requires the amount of the fee to be established pursuant to regulation and periodically adjusted by the director.

This bill would make legislative findings and declarations with respect to the need for expanded genetic testing of newborns in California.

This bill would delete the requirement that the director establish and adjust the newborn screening fee. The bill would require the department to ~~adopt regulations to implement the fee provisions, in consultation with the Department of Insurance and the Department of Managed Health Care~~ *convene a working group, with specified membership, to evaluate newborn and prenatal screening and billing procedures, and to report its recommendations to the department by March 1, 2005.*

~~This bill would delete the requirement that payment of fees into the fund would be subject to the terms and conditions of the health care service plan or insurance policy. The bill would require all hospital contracts for maternity care with public and private payers, except for certain Medi-Cal contracts, to be amended to ensure full payment to the hospital of the established fee amount.~~

(2) Existing law requires the Director of Health Services to establish necessary regulations and standards for hereditary disorders programs, in order to promote and protect the public health and safety. Existing law requires these standards to implement designated principles, including provisions for compensatory and civil damages for an individual whose confidentiality has been breached as a result of a violation of the Hereditary Disorders Act, as well as an award of attorney's fees and litigation costs.

This bill would revise the above provisions and would additionally provide for imprisonment, a fine, or both, for the knowing breach of confidentiality of an individual tested under the act. By creating a new crime, the bill would impose a state-mandated local program.



(3) Existing law requires the State Department of Health Services to establish a genetic disease unit to coordinate all departmental programs in the area of genetic disease. Existing law requires the genetic disease unit to evaluate and prepare recommendations on the implementation of tests for the detection of certain hereditary and congenital diseases.

This bill would add biotinidase disorders of fatty and organic acid metabolism to the diseases for which the genetic disease unit is required to evaluate and prepare recommendations.

This bill would require the department to expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia, and to provide information with respect to these disorders and testing resources to all women receiving prenatal care and admitted to a hospital for delivery. If the department is unable to provide statewide screening for these disorders by July 1, 2005, the bill would require the department to temporarily obtain statewide screening for these disorders from one or more laboratories, through a competitive bid process. The bill would also enact related reporting requirements.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) Birth defects are the leading cause of infant death in
4 California and the United States.

5 (b) In California, more than 530,000 babies are born each year.
6 According to the California Birth Defects Monitoring Program,
7 one in 33 will be born with a debilitating condition. Of these, one
8 in 11 will die.

9 (c) Each year, newborn screen programs in all states test four
10 million newborns to identify those who may have specific genetic
11 and metabolic disorders that could threaten their life or long-term

1 health and development. An estimated one in 3,000 newborn
2 children carries a metabolic disorder that interferes with the
3 growing child's development. California conducts newborn
4 screening for the following disorders: phenylketonuria,
5 galactosemia, sickle cell disease, and congenital hypothyroidism.
6 Since 1980, more than 5,500 cases of these disorders have been
7 detected from a small blood sample collected from each newborn
8 shortly after birth. Without early detection and dietary treatment,
9 children affected with these genetic conditions may suffer serious
10 illness, severe physical or developmental disability, and death. The
11 state's newborn screening program has proven effective in
12 reducing the incidence of morbidity and mortality resulting from
13 these four disorders.

14 (d) Recent technological advances make it possible and
15 affordable to screen for larger numbers of treatable metabolic
16 disorders, more than 20 from a single sample. At least 26 states
17 have implemented this new technology, tandem mass
18 spectrometry. After being the national leader for many years,
19 California has fallen far behind in its efforts to prevent infant
20 morbidity and mortality caused by treatable metabolic disorders.
21 At least 40 states now screen their newborns for more preventable
22 disorders than California.

23 (e) In 2002–03, the Genetic Disease Branch (GDB) of the State
24 Department of Health Services conducted a pilot project to expand
25 newborn screening to 30 disorders.

26 (f) According to the Centers for Disease Control and
27 Prevention, the average lifetime cost of providing services to a
28 person with moderate mental retardation is \$1,014,000. For every
29 20 additional cases identified through expanded screening,
30 average lifetime cost savings could exceed \$20,000,000.
31 Approximately 38 percent of infants born in California are eligible
32 for Medi-Cal. Thus, significant costs are incurred by the state for
33 providing medical care, special education, developmental
34 services, and physical and speech, or occupational therapies to
35 children with untreated disorders. Health plans, insurance
36 companies, and individual families also incur major costs.

37 (g) Cost-benefit analyses have repeatedly found that expanded
38 newborn screening produces significant net benefits. The GDB
39 estimates that for every dollar spent on expanded screening, two

1 dollars and fifty-nine cents (\$2.59) is saved in average lifetime
2 costs. Moreover, expanded screening will save lives.

3 SEC. 2. Section 124977 of the Health and Safety Code is
4 amended to read:

5 124977. (a) It is the intent of the Legislature that, unless
6 otherwise specified, the program carried out pursuant to this
7 chapter be fully supported from fees collected for services
8 provided by the program.

9 (b) (1) The department shall charge a fee to all payers for any
10 tests or activities performed pursuant to this chapter. The amount
11 of the fee shall be established by regulation and periodically
12 adjusted by the director in order to meet the costs of this chapter.
13 Notwithstanding any other provision of law, any fees charged for
14 screening and followup services provided to persons enrolled for
15 the Medi-Cal program, health care service plan enrollees, or
16 persons covered by health insurance policies, shall be paid in full
17 directly to the Genetic Disease Testing Fund. ~~Notwithstanding any~~
18 ~~other provision of law, the department shall adopt regulations to~~
19 ~~implement this section, in consultation with the Department of~~
20 ~~Insurance and the Department of Managed Health Care. Fund~~
21 *subject to all terms and conditions of each enrollee's or insured's*
22 *health care service plan or insurance coverage, whichever is*
23 *applicable, including, but not limited to, copayments and*
24 *deductibles applicable to these services, and only if these*
25 *copayments, deductibles, or limitations are disclosed to the*
26 *subscriber or enrollee pursuant to the disclosure provisions of*
27 *Section 1363.*

28 (2) The department shall expeditiously undertake all steps
29 necessary to implement the fee collection process, including
30 personnel, contracts, and data processing, so as to initiate the fee
31 collection process at the earliest opportunity.

32 (3) *The director shall convene, in the most cost-efficient*
33 *manner and using existing resources, a working group comprised*
34 *of health insurance, health care service plan, hospital, consumer,*
35 *and department representatives, to evaluate newborn and prenatal*
36 *screening fee billing procedures, and recommend to the*
37 *department ways to improve these procedures in order to improve*
38 *efficiencies and enhance revenue collections for the department*
39 *and hospitals. In performing its duties, the working group may*

1 *consider models in other states. The working group shall make its*
2 *recommendations by March 1, 2005.*

3 (4) Effective for services provided on and after July 1, 2002,
4 the department shall charge a fee to the hospital of birth, or, for
5 births not occurring in a hospital, to families of the newborn, for
6 newborn screening and followup services. The hospital of birth
7 and families of newborns born outside the hospital shall make
8 payment in full to the Genetic Disease Testing Fund.
9 ~~Notwithstanding any other provision of law, hospital contracts for~~
10 ~~maternity care with public and private payers, with the exception~~
11 ~~of Medi-Cal contracts, that do not provide for full payment to the~~
12 ~~hospital of the amount established by regulation shall be amended~~
13 ~~to ensure full payment of the amount established by regulation to~~
14 ~~the hospital.~~ The department shall not charge or bill Medi-Cal
15 beneficiaries for services provided under this chapter.

16 (c) (1) The Legislature finds that timely implementation of
17 changes in genetic screening programs and continuous
18 maintenance of quality statewide services requires expeditious
19 regulatory and administrative procedures to obtain the most
20 cost-effective electronic data processing, hardware, software
21 services, testing equipment, and testing and followup services.

22 (2) The expenditure of funds from the Genetic Disease Testing
23 Fund for these purposes shall not be subject to Section 12102 of,
24 and Chapter 2 (commencing with Section 10290) of Part 2 of
25 Division 2 of, the Public Contract Code, or to Division 25.2
26 (commencing with Section 38070). The department shall provide
27 the Department of Finance with documentation that equipment
28 and services have been obtained at the lowest cost consistent with
29 technical requirements for a comprehensive high-quality
30 program.

31 (d) (1) The department may adopt emergency regulations in
32 accordance with Chapter 3.5 (commencing with Section 11340) of
33 Part 1 of Division 3 of Title 2 of the Government Code. For the
34 purposes of the Administrative Procedure Act, the adoption of
35 regulations shall be deemed an emergency and necessary for the
36 immediate preservation of the public peace, health and safety, or
37 general welfare. Notwithstanding Chapter 3.5 (commencing with
38 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
39 Code, these emergency regulations shall not be subject to the
40 review and approval of the Office of Administrative Law.

1 Notwithstanding Section 11346.1 and Section 11349.6 of the
2 Government Code, the department shall submit these regulations
3 directly to the Secretary of State for filing. The regulations shall
4 become effective immediately upon filing by the Secretary of
5 State. Regulations shall be subject to public hearing within 120
6 days of filing with the Secretary of State and shall comply with
7 Sections 11346.8 and 11346.9 of the Government Code or shall be
8 repealed.

9 (2) The Office of Administrative Law shall provide for the
10 printing and publication of these regulations in the California
11 Code of Regulations. Notwithstanding Chapter 3.5 (commencing
12 with Section 11340) of Part 1 of Division 3 of Title 2 of the
13 Government Code, the regulations adopted pursuant to this
14 chapter shall not be repealed by the Office of Administrative Law
15 and shall remain in effect until revised or repealed by the
16 department.

17 (3) The Legislature finds and declares that the health and safety
18 of California newborns is in part dependent on an effective and
19 adequately staffed genetic disease program, the cost of which shall
20 be supported by the fees generated by the program.

21 SEC. 3. Section 124980 of the Health and Safety Code is
22 amended to read:

23 124980. The director shall establish any regulations and
24 standards for hereditary disorders programs as the director deems
25 necessary to promote and protect the public health and safety.
26 Standards shall include licensure of master level genetic
27 counselors and doctoral level geneticists. Regulations adopted
28 shall implement the principles established in this section. These
29 principles shall include, but not be limited to, the following:

30 (a) The public, especially communities and groups particularly
31 affected by programs on hereditary disorders, should be consulted
32 before any regulations and standards are adopted by the
33 department.

34 (b) The incidence, severity, and treatment costs of each
35 hereditary disorder and its perceived burden by the affected
36 community should be considered and, where appropriate, state and
37 national experts in the medical, psychological, ethical, social, and
38 economic effects or programs for the detection and management
39 of hereditary disorders shall be consulted by the department.

1 (c) Information on the operation of all programs on hereditary
2 disorders within the state, except for confidential information
3 obtained from participants in the programs, shall be open and
4 freely available to the public.

5 (d) Clinical testing procedures established for use in programs,
6 facilities, and projects shall be accurate, provide maximum
7 information, and the testing procedures selected shall produce
8 results that are subject to minimum misinterpretation.

9 (e) No test or tests may be performed on any minor over the
10 objection of the minor's parents or guardian, nor may any tests be
11 performed unless the parent or guardian is fully informed of the
12 purposes of testing for hereditary disorders and is given reasonable
13 opportunity to object to the testing.

14 (f) No testing, except initial screening for phenylketonuria
15 (PKU) and other diseases that may be added to the newborn
16 screening program, shall require mandatory participation, and no
17 testing programs shall require restriction of childbearing, and
18 participation in a testing program shall not be a prerequisite to
19 eligibility for, or receipt of, any other service or assistance from,
20 or to participate in, any other program, except where necessary to
21 determine eligibility for further programs of diagnoses of or
22 therapy for hereditary conditions.

23 (g) Pretest and posttest counseling services for hereditary
24 disorders shall be available through the program or a referral
25 source for all persons determined to be or who believe themselves
26 to be at risk for a hereditary disorder. Genetic counseling shall be
27 provided by a physician, a certified advanced practice nurse with
28 a genetics specialty, or other appropriately trained licensed health
29 care professional and shall be nondirective, shall emphasize
30 informing the client, and shall not require restriction of
31 childbearing.

32 (h) All participants in programs on hereditary disorders shall be
33 protected from undue physical and mental harm, and except for
34 initial screening for phenylketonuria (PKU) and other diseases
35 that may be added to newborn screening programs, shall be
36 informed of the nature of risks involved in participation in the
37 programs, and those determined to be affected with genetic disease
38 shall be informed of the nature, and where possible the cost, of
39 available therapies or maintenance programs, and shall be

1 informed of the possible benefits and risks associated with these
2 therapies and programs.

3 (i) All testing results and personal information generated from
4 hereditary disorders programs shall be made available to an
5 individual over 18 years of age, or to the individual's parent or
6 guardian. If the individual is a minor or incompetent, all testing
7 results that have positively determined the individual to either
8 have, or be a carrier of, a hereditary disorder shall be given through
9 a physician or other source of health care.

10 (j) All testing results and personal information from hereditary
11 disorders programs obtained from any individual, or from
12 specimens from any individual, shall be held confidential and be
13 considered a confidential medical record except for information
14 that the individual, parent, or guardian consents to be released,
15 provided that the individual is first fully informed of the scope of
16 the information requested to be released, of all of the risks,
17 benefits, and purposes for the release, and of the identity of those
18 to whom the information will be released or made available,
19 except for data compiled without reference to the identity of any
20 individual, and except for research purposes, provided that
21 pursuant to Subpart A (commencing with Section 46.101) of Part
22 46 of Title 45 of the Code of Federal Regulations entitled "Basic
23 HHS Policy for Protection of Human Subjects," the research has
24 first been reviewed and approved by an institutional review board
25 that certifies the approval to the custodian of the information and
26 further certifies that in its judgment the information is of such
27 potentially substantial public health value that modification of the
28 requirement for legally effective prior informed consent of the
29 individual is ethically justifiable.

30 (k) A physician providing information to patients on expanded
31 newborn screening shall disclose to the parent the physician's
32 financial interest, if any, in the laboratory to which the patient is
33 being referred.

34 (l) An individual whose confidentiality has been breached as a
35 result of any violation of the provisions of the Hereditary
36 Disorders Act, as defined in subdivision (b) of Section 27, may
37 recover compensatory and civil damages. Any person who
38 negligently breaches the confidentiality of an individual tested
39 under this article shall be subject to civil damages of not more than
40 ten thousand dollars (\$10,000), reasonable attorney's fees, and the

1 costs of litigation. Any person who knowingly breaches the
2 confidentiality of an individual tested under this article shall be
3 subject to payment of compensatory damages, and in addition,
4 may be subject to civil damages of fifty thousand dollars
5 (\$50,000), reasonable attorney's fees, and the costs of litigation,
6 or imprisonment in the county jail of not more than one year. If the
7 offense is committed under false pretenses, the person may be
8 subject to a fine of not more than one hundred thousand dollars
9 (\$100,000), imprisonment in the county jail of not more than one
10 year, or both. If the offense is committed with the intent to sell,
11 transfer, or use individually identifiable health information for
12 commercial advantage, personal gain, or malicious harm, the
13 person may be subject to a fine of not more than two hundred fifty
14 thousand dollars (\$250,000), imprisonment in the county jail of
15 not more than one year, or both.

16 (m) "Genetic counseling" as used in this section shall not
17 include communications that occur between patients and
18 appropriately trained and competent licensed health care
19 professionals, such as physicians, registered nurses, and
20 physicians assistants who are operating within the scope of their
21 license and qualifications as defined by their licensing authority.

22 SEC. 4. Section 125000 of the Health and Safety Code is
23 amended to read:

24 125000. (a) It is the policy of the State of California to make
25 every *reasonable* effort to detect, as early as possible,
26 phenylketonuria and all other preventable heritable or congenital
27 disorders leading to mental retardation or physical defects.

28 The department shall establish a genetic disease unit, that shall
29 coordinate all programs of the department in the area of genetic
30 disease. The unit shall promote a statewide program of
31 information, testing, and counseling services and shall have the
32 responsibility of designating tests and regulations to be used in
33 executing this program.

34 The information, tests, and counseling for children shall be in
35 accordance with accepted medical practices and shall be
36 administered to each child born in California once the department
37 has established appropriate regulations and testing methods. The
38 information, tests, and counseling for pregnant women shall be in
39 accordance with accepted medical practices and shall be offered
40 to each pregnant woman in California once the department has

1 established appropriate regulations and testing methods. These
 2 regulations shall follow the standards and principles specified in
 3 Section 124980. The department may provide laboratory testing
 4 facilities or contract with any laboratory that it deems qualified to
 5 conduct tests required under this section. However,
 6 notwithstanding Section 125005, provision of laboratory testing
 7 facilities by the department shall be contingent upon the provision
 8 of funding therefor by specific appropriation to the Genetic
 9 Disease Testing Fund enacted by the Legislature. If moneys
 10 appropriated for purposes of this section are not authorized for
 11 expenditure to provide laboratory facilities, the department may
 12 nevertheless contract to provide laboratory testing services
 13 pursuant to this section and shall perform laboratory services,
 14 including, but not limited to, quality control, confirmatory, and
 15 emergency testing, necessary to ensure the objectives of this
 16 program.

17 (b) The department shall charge a fee for any tests performed
 18 pursuant to this section. The amount of the fee shall be established
 19 and periodically adjusted by the director in order to meet the costs
 20 of this section.

21 (c) The department shall inform all hospitals or physicians and
 22 surgeons, or both, of required regulations and tests and may alter
 23 or withdraw any of these requirements whenever sound medical
 24 practice so indicates. To the extent practicable, the department
 25 shall provide notice to hospitals and other payers in advance of any
 26 increase in the fees charged for the program.

27 (d) This section shall not apply if a parent or guardian of the
 28 newborn child objects to a test on the ground that the test conflicts
 29 with his or her religious beliefs or practices.

30 (e) The genetic disease unit is authorized to make grants or
 31 contracts or payments to vendors approved by the department for
 32 all of the following:

- 33 (1) Testing and counseling services.
- 34 (2) Demonstration projects to determine the desirability and
 35 feasibility of additional tests or new genetic services.
- 36 (3) To initiate the development of genetic services in areas of
 37 need.
- 38 (4) To purchase or provide genetic services from any sums as
 39 are appropriated for this purpose.



(f) The genetic disease unit shall evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, including, but not limited to, biotinidase deficiency and cystic fibrosis. The genetic disease unit shall also evaluate and prepare recommendations on the availability and effectiveness of preventative followup interventions, including the use of specialized medically necessary dietary products.

It is the intent of the Legislature that funds for the support of the evaluations and recommendations required pursuant to this subdivision, and for the activities authorized pursuant to subdivision (e), shall be provided in the annual Budget Act appropriation from the Genetic Disease Testing Fund.

(g) Health care providers that contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership, may provide, without contracting with the department, any or all of the testing and counseling services required to be provided under this section or the regulations adopted pursuant thereto, if the services meet the quality standards and adhere to the regulations established by the department and the plan pays that portion of a fee established under this section that is directly attributable to the department's cost of administering the testing or counseling service and to any required testing or counseling services provided by the state for plan members. The payment by the plan, as provided in this subdivision, shall be deemed to fulfill any obligation the provider or the provider's patient may have to the department to pay a fee in connection with the testing or counseling service.

(h) The department may appoint experts in the area of genetic screening, including, but not limited to, cytogenetics, molecular biology, prenatal, specimen collection, and ultrasound to provide expert advice and opinion on the interpretation and enforcement of regulations adopted pursuant to this section. These experts shall be designated agents of the state with respect to their assignments. These experts shall receive no salary, but shall be reimbursed for expenses associated with the purposes of this section. All expenses of the experts for the purposes of this section shall be paid from the Genetic Disease Testing Fund.

SEC. 5. Section 125001 of the Health and Safety Code is amended to read:

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic screening and followup services for persons who have the screening.

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia as soon as possible. The department shall provide information with respect to these disorders and testing resources available, to all women receiving prenatal care and to all women admitted to a hospital for delivery. If the department is unable to provide this statewide screening by July 1, 2005, the department shall temporarily obtain these testing services through a competitive bid process from one or more public or private laboratories that meet the department's requirements for testing, quality assurance, and reporting. If the department determines that contracting for these services is more cost-effective, and meets the other requirements of this chapter, than purchasing the tandem mass spectrometry equipment themselves, the department shall contract with one or more public or private laboratories.

(c) The department shall report to the Legislature regarding the progress of the program on or before July 1, 2006. The report shall include the costs for screening, followup, and treatment as compared to costs and morbidity averted for each condition tested for in the program.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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